DEPARTMENT OF THE AIR FORCE
59TH MEDICAL WING (AETC)
JOINT BASE SAN ANTONIO - LACKLAND TEXAS

11 APR 2016

MEMORANDUM FOR 959 MDOS
ATTN: MAJ ADRIENNE LAURY

FROM: 59 MDW/SGVU

SUBJECT: Professional Presentation Approval

1. Your paper, entitled **Balloon Dilation of Sinus Ostia in the Department of Defense: Diagnoses, Actual Indications, and Outcomes** presented at **International Forum of Allergy and Rhinology and Combined Otolaryngology Spring Meeting, Chicago, IL 18-22 May 2016** with MDWI 41-108, and has been assigned local file #**16142.**

2. Pertinent biographic information (name of author(s), title, etc.) has been entered into our computer file. Please advise us (by phone or mail) that your presentation was given. At that time, we will need the date (month, day and year) along with the location of your presentation. It is important to update this information so that we can provide quality support for you, your department, and the Medical Center commander. This information is used to document the scholarly activities of our professional staff and students, which is an essential component of Wilford Hall Ambulatory Surgical Center (WHASC) internship and residency programs.

3. Please know that if you are a Graduate Health Sciences Education student and your department has told you they cannot fund your publication, the 59th Clinical Research Division may pay for your basic journal publishing charges (to include costs for tables and black and white photos). We cannot pay for reprints. If you are 59 MDW staff member, we can forward your request for funds to the designated wing POC.

4. Congratulations, and thank you for your efforts and time. Your contributions are vital to the medical mission. We look forward to assisting you in your future publication/presentation efforts.

Linda Steel-Goodwin

LINDA STEEL-GOODWIN, Col, USAF, BSC
Director, Clinical Investigations & Research Support

PROCESSING OF PROFESSIONAL MEDICAL RESEARCH/TECHNICAL PUBLICATIONS/PRESENTATIONS

1. TO: CLINICAL RESEARCH	2. FROM: (Author's Name, Rank, Grade, Office Symbol)	3. GME/GHSE STUDENT:	4. PROTOCOL NUMBER:
	Laury, Adrienne, Maj, O4	☐ YES ☒ NO	FWH20150089E

5. PROTOCOL TITLE: (NOTE: For each new release of medical research or technical information as a publication/presentation, a new 59 MDW Form 3039 must be submitted for review and approval.)

Balloon Sinuplasty: Indications, Outcomes and Complications in the Department of Defense

6. TITLE OF MATERIAL TO BE PUBLISHED OR PRESENTED:

Balloon Dilation of Sinus Ostia in the Department of Defense: Diagnoses, Actual Indications, and Outcomes

7. FUNDING RECEIVED FOR THIS STUDY? ☐ YES ☒ NO FUNDING SOURCE:

8. DO YOU NEED FUNDING SUPPORT FOR PUBLICATION PURPOSES: ☐ YES ☒ NO

9. IS THIS MATERIAL CLASSIFIED? ☐ YES ☒ NO

10. IS THIS MATERIAL SUBJECT TO ANY LEGAL RESTRICTIONS FOR PUBLICATION OR PRESENTATION THROUGH A COLLABORATIVE RESEARCH AND DEVELOPMENT AGREEMENT (CRADA), MATERIAL TRANSFER AGREEMENT (MTA), INTELLECTUAL PROPERTY RIGHTS AGREEMENT ETC.?
☐ YES ☒ NO NOTE: If the answer is YES then attach a copy of the Agreement to the Publications/Presentations Request Form.

11. MATERIAL IS FOR: ☒ DOMESTIC RELEASE ☐ FOREIGN RELEASE
CHECK APPROPRIATE BOX OR BOXES FOR APPROVAL WITH THIS REQUEST. ATTACH COPY OF MATERIAL TO BE PUBLISHED/PRESENTED.

☒ 11a. PUBLICATION/JOURNAL (List intended publication/journal.)
International Forum of Allergy and Rhinology

☐ 11b. PUBLISHED ABSTRACT (List intended journal.)

☐ 11c. POSTER (To be demonstrated at meeting: name of meeting, city, state, and date of meeting.)

☒ 11d. PLATFORM PRESENTATION (At civilian institutions: name of meeting, state, and date of meting.)
Combined Otolaryngology Spring Meeting, Chicago, IL; May 18-22, 2016

☐ 11e. OTHER (Describe: name of meeting, city, state, and date of meeting.)

12. EXPECTED DATE WHEN YOU WILL NEED THE CRD TO SUBMIT YOUR CLEARED PRESENTATION/PUBLICATION TO DTIC
NOTE: All publications/presentations are required to be placed in the Defense Technical Information Center (DTIC).

DATE	
4/1/2016	

13. 59 MDW PRIMARY POINT OF CONTACT (Last Name, First Name, M.I., email)	14. DUTY PHONE/PAGER NUMBER
Laury, Adrienne M, adrienne.m.laury.mil@mail.mil	210-916-8040/ 210-594-2630

15. AUTHORSHIP AND CO-AUTHOR(S) List in the order they will appear in the manuscript.

LAST NAME, FIRST NAME AND M.I.	GRADE/RANK	SQUADRON/GROUP/OFFICE SYMBOL	INSTITUTION (If not 59 MDW)
a. Primary/Corresponding Author Laury, Adrienne	Maj/O4	959 MDOS	
b. Bowe, Sarah	Maj/O4	959 MDOS	
c. Stramiello, Joshua	--		South Florida SOM
d. Mcmains, Kevin	--		BAMC
e.			
f.			

I CERTIFY ANY HUMAN OR ANIMAL RESEARCH RELATED STUDIES WERE APPROVED AND PERFORMED IN STRICT ACCORDANCE WITH 32 CFR 219, AFMAN 40-401_IP, AND 59 MDWI 41-108. I HAVE READ THE FINAL VERSION OF THE ATTACHED MATERIAL AND CERTIFY THAT IT IS AN ACCURATE MANUSCRIPT FOR PUBLICATION AND/OR PRESENTATION.

16. AUTHOR'S PRINTED NAME, RANK, GRADE	17. AUTHOR'S SIGNATURE	18. DATE
Adrienne Laury, Maj, O4	LAURY.ADRIENNE.M.1260383062	3/22/2016
19. APPROVING AUTHORITY'S PRINTED NAME, RANK, TITLE Steve Matura, Lt Col, OS	20. APPROVING AUTHORITY'S SIGNATURE	21. DATE 3/24/16

PROCESSING OF PROFESSIONAL MEDICAL RESEARCH/TECHNICAL PUBLICATIONS/PRESENTATIONS

1st ENDORSEMENT (59 MDW/SGVU Use Only)

TO: Clinical Research Division 59 MDW/CRD Contact 292-7141 for email instructions.	22. DATE RECEIVED 3/25/2016	23. ASSIGNED PROCESSING REQUEST FILE NUMBER 16142
24. DATE REVIEWED 25 MAR 2016		25. DATE FORWARDED TO 502 ISG/JAC

26. AUTHOR CONTACTED FOR RECOMMENDED OR NECESSARY CHANGES: ☒ NO ☐ YES If yes, give date _____ ☐ N/A

27. COMMENTS ☒ APPROVED ☐ DISAPPROVED

The manuscript is approved.

28. PRINTED NAME, RANK/GRADE, TITLE OF REVIEWER	29. REVIEWER SIGNATURE	30. DATE
Rocky CALCOTE, PhD CLINICAL RESEARCH ADMINISTRATOR	Rocky Calcote	25 MAR 2016

2nd ENDORSEMENT (502 ISG/JAC Use Only)

31. DATE RECEIVED	32. DATE FORWARDED TO 59 MDW/PA
25 Mar 16	28 MAR 16

33. COMMENTS ☒ APPROVED (In compliance with security and policy review directives.) ☐ DISAPPROVED

The abstract requires the proper disclaimer.

34. PRINTED NAME, RANK/GRADE, TITLE OF REVIEWER	35. REVIEWER SIGNATURE	36. DATE
M.E. Coon, O-4, USAF		28MAR16

3rd ENDORSEMENT (59 MDW/PA Use Only)

37. DATE RECEIVED	38. DATE FORWARDED TO 59 MDW/SGVU
31 March 2016	31 March 2016

39. COMMENTS ☑ APPROVED (In compliance with security and policy review directives.) ☐ DISAPPROVED

40. PRINTED NAME, RANK/GRADE, TITLE OF REVIEWER	41. REVIEWER SIGNATURE	42. DATE
Christopher Carwile, TSgt/E-6, NCOIC, PA	CARWILE.CHRISTOPHER.STEWART.1280477229	31 March 2016

4th ENDORSEMENT (59 MDW/SGVU Use Only)

43. DATE RECEIVED	44. SENIOR AUTHOR NOTIFIED BY PHONE OF APPROVAL OR DISAPPROVAL ☐ YES ☐ NO ☐ COULD NOT BE REACHED ☐ LEFT MESSAGE

45. COMMENTS ☐ APPROVED ☐ DISAPPROVED

46. PRINTED NAME, RANK/GRADE, TITLE OF REVIEWER	47. REVIEWER SIGNATURE	48. DATE

Balloon Dilation of Sinus Ostia in the Department of Defense: Diagnoses, Actual Indications, and Outcomes

Adrienne M. Laury, MD[1], Sarah N. Bowe, MD[1], Joshua Stramiello, BS[2], and Kevin C. McMains, MD[1]

[1] Department of Otolaryngology-Head and Neck Surgery, San Antonio Uniformed Services Health Education Consortium (SAUSHEC), Ft. Sam Houston, TX, USA

[2] University of South Florida Morsani College of Medicine, Tampa, FL, USA

Corresponding Author: Adrienne M. Laury MD

Address: ATTN: MCHE-SDT (Otolaryngology)
3551 Roger Brooke Drive
San Antonio Military Medical Center
JBSA- Ft. Sam Houston, TX 78234

Phone: 210-916-2367

Fax: 210-916-1247

Email: Adrienne.laury@gmail.com

Keywords: Balloon dilation, sinus surgery, sinusitis, disease severity

The views expressed herein are those of the authors and do not reflect the official policy or position of Brooke Army Medical Center, the U.S. Army Medical Department, the U.S. Army Office of the Surgeon General, the Department of the Army, the Department of Defense, or the U.S. Government.

Abstract:

Introduction: In the past decade, increasing evidence has supported the use of balloon catheter dilation (BCD) of sinus ostia in the treatment of chronic and recurrent acute rhinosinusitis. However, this technology is often advertised and utilized for off-label indications, which lack evidence-based support. Therefore, we sought to evaluate "actual" indications for BCD in a profit-blind healthcare system – the Department of Defense (DoD).

Methods: A retrospective review was performed on 319 consecutive patients who underwent BCD in the DoD from January 1, 2011 - December 31, 2013. All charts were reviewed for ICD-9 diagnoses, presence of chronic rhinosinusitis (CRS) defined by the European Position Paper on Rhinosinusitis and Nasal Polyps (EPOS), pre-op Lund-Mackay scores, nasal endoscopy findings, sinuses dilated, post-operative outcomes, and complications.

Results: Of the 319 patients identified, 217 had sufficient documentation to be included. A CRS ICD-9 code was applied in 182/217 (83.9%) and recurrent acute rhinosinusitis in 12/217 (5.6%). Only 50.5% of CRS patient charts met criteria using EPOS guidelines. In contrast, 39.6% met the ICD-9 criteria for atypical facial pain. Patients with Lund-Mackay scores ≤ 4 were reviewed for number of sinuses dilated. Eighty-eight of 123 patients (71.5%) had sinuses dilated that were free from opacification/mucosal edema on pre-operative imaging.

Conclusion: Balloon dilation of sinus ostia has an expanding role in treating sinus disease. In the studied population, BCD is often utilized for off-label indications for which there is currently no evidence. Future studies are needed to evaluate the efficacy of this technology in treating these alternate indications.

Introduction

Over the past decade, balloon catheter dilation (BCD) of sinus ostia has become an increasingly popular technique in the treatment of various sinonasal diseases. Current literature suggests that BCD can safely dilate frontal, sphenoid, and maxillary sinuses with preservation of ostial patency for up to two years.[1-4] Additionally, a recent meta-analysis demonstrated that balloon catheter dilation for chronic rhinosinusitis (CRS) has a positive impact on patient quality of life.[5]

Currently, there are three companies with FDA-approved balloon dilation systems - Acclarent Inc. (Menlo Park, CA), Entellus Medical (Plymouth, MN), and Medtronic (Dublin, Ireland). Per their FDA approvals, these systems are "intended to dilate sinus ostia…for diagnostic and therapeutic procedures", but are not restricted to the treatment of only certain disease states or pathologies.[6] Yet, nearly all clinical trials utilizing these systems, have focused primarily on the use of BCD in the treatment of chronic and recurrent acute rhinosinusitis in adults and children.[1-3,7] Of interest, over the past few years, BCD has been increasingly advertised and implemented for the treatment of alternate/"off-label" diagnoses such as: migraine, nasal congestion, facial pain, snoring, obstructive sleep apnea, and headache.[8-11] As noted, clinical trials have not been performed to confirm its efficacy for these indications.

Therefore, in light of this more liberal use of BCD, we sought to investigate the primary diagnoses for which this technology is actually being utilized in a "profit blind" healthcare system – the Department of Defense (DoD). Secondary aims included evaluating whether diagnoses were accurately applied, correlating the sinuses dilated with objective evidence of disease, and evaluating the outcomes and complications, if any, of BCD in this patient population.

Methods

Institutional Review Board approval was obtained from the 59th Medical Wing prior to initiation of the study. Subsequently, three hundred and nineteen consecutive active duty patients were identified who underwent BCD of sinus ostia between January 1, 2011 and December 31, 2013. These patients were identified based on CPT codes – 31295, 31296, 31297 and active duty status at the time of the procedure. Once identified, each patient's medical record was reviewed for pre-operative visit, primary ICD-9 diagnosis, and sinuses dilated. On initial screening, if any of these items were not accessible in the medical record, the patient was excluded from analysis.

Following initial review, 217 active duty patients were included in the study and their medical records evaluated. First, each chart was evaluated for patient age and medical treatment facility at which BCD was performed, as well as clinic vs operating room setting. Each record was then evaluated for the ICD-9 diagnosis for which the BCD was being performed. In the case where chronic rhinosinusitis (CRS) was the assigned diagnosis, the pre-operative records were then reviewed to see if that diagnosis was actually appropriately assigned based on the definition of CRS specified by the European Position Paper on Rhinosinusitis and Nasal Polyps (EPOS 2012). This definition includes: 2 or more symptoms of congestion, nasal discharge, facial pain/pressure, reduction in smell AND either endoscopic signs of disease OR CT changes consistent with disease. [12] If the medical records did not include enough information to make this diagnosis, another presumptive diagnosis was then assigned based solely on the information provided in the medical record including symptoms, physical exam, and imaging.

Post-operative symptoms were also recorded for each patient. Endoscopy evaluations and findings were noted, as were pre-operative CT findings including Lund-Mackay score for each patient with imaging. Additionally, the sinuses dilated were also recorded, as well as the inclusion of any other procedures at the time of the BCD. Patients with Lund-Mackay scores of 4 or less were then further evaluated regarding which sinuses were dilated. Four was chosen as a cut-off as it is the lowest number possible that could potentially warrant BCD of 4 different sinuses. This would allow for dilation of bilateral maxillary and frontals, which were the most commonly dilated sinus ostia (with sphenoid dilation only making up 5.5% of dilations in this patient population). These patients' CT scans and endoscopy reports were reviewed to identify the specific sinuses in which disease was present and compared against those in which BCD was performed.

Finally, post-operative records were also evaluated for change in pre-operative symptoms after the procedure as well as any complications from the BCD. Descriptive statistics were performed on demographic information, as well as patient symptoms, diagnosis, work-up, management, and complications.

Results

Of the 319 records reviewed, 217 active duty service members underwent BCD of sinus ostia and had complete medical records of sufficient detail for evaluation. Mean patient age was 38.6 years (range 20-58). One hundred and seventy four patients were male (80.2%) vs 43 (19.8%) which were female. A total of 38 different military installations around the world documented the use of BCD of sinus ostia. Four installations accounted for approximately 50% of the

procedures. These were: Blanchfield Army Community Hospital (21.2%) (Fort Campbell, KY), Fort Belvoir Community Hospital (14.3%) (Fort Belvoir, VA), Naval Medical Center San Diego (6.9%) (San Diego, CA), and Womack Army Medical Center (6.5%) (Fort Bragg, NC).

All patients were seen in the clinic prior to the BCD procedure. No patient had a validated sinonasal questionnaire recorded in their medical record prior to BCD. Patients often had multiple symptoms reported in their history and all available symptoms were recorded. Facial pain/pressure and nasal congestion were the two most common symptoms, noted in 73.7% and 71.5%, respectively (Figure 1). Only 65.4% (142/217) of patients underwent documented pre-operative nasal endoscopy. Table 1 shows the most common abnormal findings on nasal endoscopy, again allowing for the possibility of a single patient having multiple abnormal findings. Seventy-two patients (50.7% of the patients who underwent endoscopy) had normal endoscopy documented.

The ICD-9 diagnosis assigned to each patient at the visit prior to the BCD is noted in Figure 2. If multiple diagnoses were found, the one for which the BCD was being performed was selected based on the plan in the medical record. Chronic rhinosinusitis was most common (83.9%, 182/217), followed by recurrent acute rhinosinusitis (5.5%, 12/217), nasal polyposis (3.7%, 8/217), sinus barotrauma (3.2%, 7/217), headache (1.8%, 4/217), nasal airway obstruction (1.4%, 3/217), and allergic rhinitis (0.5%, 1/217).

Patient charts with the diagnosis of CRS were then further evaluated for fulfillment of the EPOS 2012 criteria for CRS. Of the 182 originally assigned the diagnosis of CRS, only 92 (50.5%) actually fulfilled the EPOS requirements, based on documentation. Based solely on the history, physical examination, and imaging available in the medical record, alternate ICD-9 diagnoses that would be considered appropriate were assigned (Figure 3).

Patients underwent BCD of sinus ostia anywhere from 4-489 days after their previous clinic visit. One hundred and seventy-three (79.7%) procedures were performed under general anesthesia in the operating room, while the remaining 20.3% were performed in the clinic under local anesthetic. Only 53 of 217 patients (24.4%) underwent BCD as their singular procedure. The majority underwent additional (often multiple) procedures including: turbinate reduction (113/217), septoplasty (90/217), functional endoscopic sinus surgery (FESS) (84/217), and rhinoplasty (21/217). Only thirty-four out of 217 (15.7%) had 1 sinus ostia dilated. Otherwise, BCD was performed on multiple sinuses. In total, 135 patients underwent maxillary dilation, while 145 underwent frontal, and 12 sphenoid.

Fifteen patients did not follow-up after the procedure. These patients were still included for analysis as all pre-procedure data points could be collected. Of the remaining 202 patients, all were seen anywhere from 4-230 days following the procedure (mean: 7 days). Post-operative complications were documented in 7.8% of patients. The most common complications were bleeding (8/217, 3.7%) and pain greater than expectation (6/217, 2.8%). Other complications included infection (1/217, 0.5%), orbital chemosis and proptosis (1/217, 0.5%), and facial subcutaneous emphysema (1/217, 0.5%). Only 2 of these complications required re-admission to the hospital. One hundred thirty three patients were seen for a second post-operative visit (range: 10-639 days after their initial procedure, mean 31 days). If documented, change between pre-operative patient symptoms and post-operative symptoms at first or second visit were recorded (Figure 4).

A subset of patients with Lund-Mackay scores of 4 or less were analyzed. One hundred and twenty three patients fit this criteria. Pre-operative CT scans and nasal endoscopy were compared to the number of sinuses dilated. Prior to BCD, 99.1% of patients underwent CT scanning.

Figure 5 shows the patients' Lund-Mackay scores and the number of sinuses actually dilated. Over 2/3 of these patients (88/123, 71.5%), had at least one sinus dilated which was free of disease by CT and endoscopy.

Discussion

Over the past decade, balloon catheter dilation of sinus ostia has gained widespread notoriety and increased utilization. Ference et al documented that over 8% of all endoscopic sinus surgeries (ESS) in 2011 employed BCD.[13] A recent survey of members of the American Rhinologic Society (ARS) indicated that otolaryngologists "are more accepting of this technology now, compared with 5 years ago, and many of them believe that their use of BCT [balloon catheter technology] will increase in the future". [14] This increase in utilization may be attributed to a variety of factors including positive clinical trials/studies, in office applicability, and lucrative financial reimbursements.[1-4,12,15] All of these, along with well-placed advertising by the balloon industry and ENT practices, have resulted in further promotion of this technology amongst otolaryngologists and their patients looking for new solutions to sinonasal problems. [16] Since its introduction, the indications for which BCD is utilized have also broadened, often without high-quality clinical trials to support this expansion. While a recent meta-analysis showed that BCD had a positive impact on quality of life, this was limited to patients who actually met the diagnostic criteria of CRS. [5] Utilizing the diagnostic information present in the medical record, over 50% of our patient population underwent BCD for diagnoses other than CRS or recurrent acute rhinosinusitis (RARS). The CRS diagnostic criteria used were the EPOS 2012. The AAO-HNS Clinical Practice Guidelines from 2007 and 2015, which are utilized as

the inclusion criteria in many of the BCD studies, are nearly identical to the EPOS CRS criteria. Based on this definition, we found that of the original 183 patients given an ICD-9 diagnosis of CRS, only 50.5% actually documented these criteria. This result raises several questions/possibilities: perhaps the criteria for the diagnosis of CRS is not as ubiquitously known as we may have thought, perhaps providers are just poor at documenting pertinent information in the medical record, or possibly ICD-9 diagnosis codes are inaccurately assigned? While the accuracy of ICD-9 diagnoses has never been examined with regards to CRS, GI literature has shown that ICD-9 codes are often incorrect (at least 31% of the time) in identifying common diagnoses.[17] This finding raises concern that patients may be undergoing procedures that are not proven efficacious for the conditions they suffer. Additional study in other practice environments would be beneficial to illuminate how widespread mis-diagnosis of this type is.

Our hypothesis that poor documentation lies as the fundamental cause of these inaccurate diagnoses is equally concerning. While insufficient documentation does not cause immediate harm, it opens the gateway for significant confusion or even potential litigation in the setting of complications. Additionally, it limits the accuracy of retrospective reviews, such as this one.

Atypical facial pain/headache accounted for 80% (72/90 patients inaccurately diagnosed with CRS) of the "off-label" use of this technology. While management of headache (without corresponding CT abnormalities) has been a long-standing challenge for the rhinologist, BCD has not been evaluated in any clinical trial as a potential treatment option for this diagnosis. Marzetti et al, evaluated the efficacy of BCD in the treatment of sinus headache, but this was in patients who also met the criteria for CRS with headache being one of their CRS-symptoms.[18] Otherwise, the literature is silent on this application of BCD. Formal study should be undertaken to assess the efficacy of BCD for this condition.

A subset of evaluated CRS patients had Lund-Mackay scores of ≤4. Since nearly all BCD studies focus on its utilization in treating sinuses with CRS or RARS, there is an expectation that treated sinuses should have had some opacification or mucosal thickening on imaging or positive endoscopy findings. Among this subset of patients, 71.5% had sinus ostia dilated that were free from both opacification and abnormal endoscopy findings. Review of the medical record did not reveal any localizing symptoms that would support intervention in these areas.

The physical location in which BCD of sinus ostia was performed in our cohort should also be noted. Nearly 50% of all procedures were performed at 4 out of 38 possible medical treatment facilities. Of these four, 3 are community hospitals and 1 is an academic medical center. This finding is consistent with findings of the previously referenced ARS survey data which showed a majority of providers performing only 1-4 balloons per month vs <10% of providers who performed >11 BCD per month.[14] In an extensive review of national Medicare data, Venkatraman, et al found Endoscopic Sinus Surgery rates varied 5 fold between hospital referral regions (HRRs).[19] This variation was present even among contiguous HRRs. In their study, higher rates of CRS diagnosis were not found to predict increased ESS within the HRRs. Taken together, these data raise questions about the multiple factors that affect the decision to proceed with surgical management of sinus disease and the particular techniques selected.

Additionally, nearly 80% of this cohort had BCD performed in the OR rather than clinic. This high OR propensity is likely secondary to the combination of BCD with other procedures. When evaluating the BCD that were performed as solo procedures, 24/53 (45.3%) were done in the OR. This is comparable to the 54% OR rate reported in the ARS survey.[14] It is worthy to note that CPT codes for BCD were approved in 2011, which corresponded with the beginning of the period studied. In the recent meta-analysis by Levy, SNOT-20 scores appeared to improve

more when BCD was performed in the OR vs the clinic.[5] This emphasizes the need for further studies to evaluate outcome differences in BCD performed in the OR vs the clinical setting as well as any changes in practice patterns following introduction of CPT codes for BCD.

The observed complication rate after BCD was almost double compared to previously reported values. In 2015, Sillers et al, identified 7 cases of hemorrhage and 2 orbital complications in 628 in-office BCD cases.[20] The higher rate described here is possibly secondary to the combination of the BCD procedure with other sinonasal procedures (ie septoplasty and FESS), which carry a higher risk of complications on their own. Of interest, the cases of serious complications (orbital chemosis/proptosis and facial subcutaneous emphysema) were both in patients who underwent BCD in isolation and who had Lund-Mackay scores of 0.

There are several potential weaknesses of this paper. First, data were obtained from a retrospective chart review, relying on the accuracy and completeness of past documentation. The data set was generated from a system-wide medical record system, which allows thorough review of all records generated. However, as mentioned above, a retrospective review is only as good as the initial documentation upon which it is based. Additionally, the completely absent utilization of a standardized outcome measure ie SNOT-20, makes comparing medical record data across patients and providers challenging. Second, all of the patients included were active duty military personnel. Given the physical selection standards and the relative youth of this population, these demographic factors may limit the generalizability of our paper. Third, because these results reflect practice in a "financially blind" healthcare system, they may not reflect patterns in other practice environments. While the studied environment removes financial incentives to maximize use of a remunerative technology, BCD use in this setting also does not require prior authorization from insurance. Paradoxically, this may open the door for potential

overuse and possible off-label utilization. Finally, the presence of confounding surgical procedures (i.e. septoplasty and turbinoplasty) makes isolating the changes due to BCD challenging.

Conclusion: This is the first study to analyze the diagnosis and management trends of BCD utilization within a clinical practice environment. From documentation present in the medical record, nearly half of all BCD patients were inappropriately classified as having fulfilled CRS criteria. The most common "off-label" condition for which BCD is being used to treat was atypical facial pain/headache. Presently, evidence is lacking to support the various diagnoses for which BCD is currently being utilized. In addition, BCD appears to be frequently employed in sinuses without evidence of disease. Future study is needed to investigate whether similar trends of incorrect diagnosis, off-label use, and treatment of non-diseased sinuses pervades in other practice settings.

References:

1. Weiss RL, Church CA, Kuhn FA, et al. Long-term outcome analysis of balloon catheter sinusotomy: two-year follow-up. Otolaryngol Head Neck Surg. 2008 Sept; 139(3 Suppl 3): S38-46.
2. Sikand A, Silvers SL, Pasha R, et al. Office-Based Balloon Sinus Dilation: 1- Year Follow-up of a Prospective, Multicenter Study. Ann Otol Rhinol Laryngol. 2015 Aug; 124(8):630-7.
3. Bikhazi N, Light J, Truitt T, Schwartz, M, Cutler J. Standalone balloon dilation versus sinus surgery for chronic rhinosinusitis: a prospective, multiceneter, randomized, controlled trial with 1-year follow-up. Anm J RHinol Allergy. 2014 Jul-Aug;28(4):323-9.
4. Chandra RK, Kern RC, Cutler JL, Welch KC, Russell PT. REMODEL larger cohort with long-term outcomes and meta-analysis of standalone balloon dilation studies. Laryngoscope. 2016 Jan;126(1):44-50.
5. Levy JM, Marino MJ, McCool ED. Paranasal Sinus Balloon Catheter Dilation for Treatment of Chronic Rhinosinusitis: A Systemic Review and Metanalysis. Otolaryngol Head Neck Surg. 2016 Jan; 154(1): 3-40.
6. Acclarent, Inc. 501(k) Summary for Relieva™ Sinus Balloon Catheter and Relieva Acella™ Sinus Balloon Catheter. 2008 Mar 11. http://www.accessdata.fda.gov/cdrh_docs/pdf7/k073041.pdf
7. Wang F, Song Y, Zhang X, Tan G. Sinus balloon catheter dilation in pediatric chronic rhinosinusitis resistant to medical therapy. JAMA Otolaryngol Head Neck Surg. 2015 Jun; 141(6):526-31.
8. Otolaryngology Group of Central Pennsylvania. Accessed: 2016 Jan 18. http://www.sinussurgerycenter.com/balloon-sinuplasty/patient-testimonials
9. EOS Sleep. Accessed: 2016 Jan 18. http://www.eossleep.com/balloon-sinuplasty/
10. Douglas M. Stevens, MD. Accessed 2015 Sep 2. http://www.douglasstevensmd.com/balloon-sinuplasty
11. Balloon Sinuplasty Glendale, CA. Accessed 2016 Jan 22. http://www.drbublik.com/services-balloon-sinuplasty.html
12. Fokkens WJ, Lund VJ, Mullol J, et al. EPOS 2012: European position paper on rhinosinusitis and nasal polyps 2012. A summary for otorhinolaryngologists. Rhinology. 2012 Mar; 50(1):1-12.
13. Ference EH, Graber M, Conley D, et al. Operative Utilization of Balloon Versus Traditional Endoscopic Sinus Surgery. Laryngoscope. 2015 Jan. 125; 49-57.
14. Halderman AA, Stokken J, Momin SR, Smith TL, Sindwani R. Attitudes on and usage of balloon catheter technology in rhinology: A survey of the American Rhinologic Society. Am J Rhino Allergy. 2015 Sept-Oct; 29(5):389-93.
15. Ference EH, Schroeder JW, Qureshi H, et al. Current Utilization of Balloon Dilation versus Endoscopic Techniques in Pediatric Sinus Surgery. Otolaryngol Head Neck Surg 2014; 151(5):852-60.
16. Batra PS, Ryan MW, Sindwani R, Marple BF. Balloon Catheter Technology in Rhiniology: Reviewing the Evidence. Laryngoscope. 2001; 121:226-232.
17. Hou JK, Tan M, Stidham RW, et al. Accuracy of diagnostic codes for identifying patients with ulcerative colitis and Crohn's disease in the Veterans Affairs Health Care System. Dig Dis Sci. 2014 Oct; 59(10):2406-10.
18. Marzetti A, Tedaldi M, Passali FM. The role of balloon sinuplasty in the treatment of sinus headache. Otolaryngol Pol. 2014 Jan-Feb; 69(1):15-9.
19. Venkatraman G1, Likosky DS, Morrison D, Zhou W, Finlayson SR, Goodman DC. Small area variation in endoscopic sinus surgery rates among the Medicare population. Arch Otolaryngol Head Neck Surg. 2011 Mar;137(3):253-7.
20. Sillers MJ, Lay KF, Holy CE. In-Office Balloon Catheter Dilation: Analysis of 628 Patients from an Administrative Claims Database. Laryngoscope. 2015 Jan;125(1):42-8.

Pre-op nasal endoscopy (n=142)	
Normal endoscopy	72
Septal Deviation	54
Turbinate hypertrophy	44
Septal perforation	2
Purulence	3
Crusting	2

Table 1: Pre-BCD nasal endoscopy findings. All findings for each patient were recorded with possibly more than one finding per patient. Seventy-five patients did not have nasal endoscopy prior to BCD.

Figure 1: Pre-BCD patient symptoms. All symptoms for each patient were recorded often resulting in more than one symptom per patient.

Figure 2: ICD-9 diagnosis assigned to patients prior to BCD.

Figure 3: Actual diagnoses of the original CRS patient cohort. CRS was defined based on the EPOS 2012 criteria. Patients who did not meet that diagnosis were reassigned to the most appropriate ICD-9 diagnosis based on symptoms present in the medical record. CRS = Chronic Rhinosinusitis

Figure 4: Post-BCD patient symptoms. Symptoms were categorized into either resolved/improved vs unchanged/worsened. Post-BCD symptoms were only documented if specifically mentioned in the medical record. Each patient could have multiple symptoms and all were recorded.

Figure 5: Number of Sinuses Dilated for Patients with Lund-Mackay Scores ≤ 4

59th Medical Wing (59th MDW)
Institutional Review Board (IRB)
59th Clinical Research Division/SGVUS/(210) 292-7143
2200 Bergquist Dr, Bldg 4430, Lackland AFB, TX 78236-9908

17 Aug 15

FINAL IRB DETERMINATION - EXEMPT STUDY:

Determination Date: 17 Aug 15

Principal Investigator: Maj Adrienne Laury/BAMC

IRB Reference Number: FWH20150089E

Protocol Title: "Balloon Sinuplasty: Indications, Outcomes, and Complications in the Department of Defense"

1. You may begin your study.

Your study, referenced above, was **determined** to be **EXEMPT** from research regulation 32 CFR 219 regarding the protection of human subjects **Category 4** (32 CFR 219.101.b.4) by the 59th Medical Wing (59 MDW), via the *exempt review/determination process* by the 59th MDW Institutional Review Board (IRB) Chairperson or designee, based on 32 CFR 219.101(b). It has been determined your research activities, involving human subjects, all fit within one or more of the following exempt category(ies):

32 CFR 219.101(b)(4) - Research involving the collection or study of: existing data, documents, and records, AND the research is minimal risk, AND the research does not involve prisoners as participants, AND **4a** the information will be recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects (e.g., codes)

Items reviewed and approved by the Designated Reviewer include:

Waiver of HIPAA Authorization
A waiver of requirement to obtain a valid authorization to use or disclose Protected Health Information (PHI) was also approved. The Designated Reviewer has determined that the following criteria as required by DoD 6025.18-r C7.9.1.1 and C7.9.2. were satisfied following the requirements of the Common Rule, including expedited review procedures (32 CFR 219.110):

(i) The PHI use or disclosure involves no more than minimal risk to the privacy of individuals based on at least the presence of (1) an adequate plan presented to the Privacy Board to protect PHI identifiers from improper use and disclosure; (2) an adequate plan to destroy those identifiers at the earliest opportunity, consistent with the research, absent a health or research justification for retaining the identifiers or if retention is otherwise required by law; and (3) adequate written assurances that the PHI will not be reused or disclosed to any other person or entity except (a) as required by law, (b) for authorized oversight of the research study, or (c) for other research for which the use or disclosure of the PHI is permitted by the Privacy Rule.

(ii)The research could not practicably be conducted without the requested waiver or alteration.

(iii)The research could not practicably be conducted without access to and use of the PHI.

Protocol
CV
CITI Training
Form A Signature Sheet
Form J HIPAA Waiver

2. **Please note: Your study has received a one-time exemption determination. You only need to contact the 59th MDW IRB in the future for the following reasons:

- You encounter an unexpected problem that could put your subjects or others at risk
- You intend to modify this study (submit an amendment to the 59crd.protocol@us.af.mil to confirm the change does not affect the exempt status of your study)

The 59th MDW IRB must be notified immediately of any additional information or changes to the protocol that may affect its category and/or risk status.

3. You must comply with the information contained in the Form A Signature Sheet, e.g., Principal Investigator's Agreement. Protection of subjects' rights safety and welfare and responsibility for protecting PHI/PII and research data now fall on the investigator and their commander as the research is exempt from human research protection regulations.

4. The 59th MDW IRB no longer requires Status Reports and Final Reports for Exempt and Non-research/Non-human Research. The PI should notify the 59th MDW IRB of any publications/ presentations resulting from a study outcome.

5. If funds were requested for your study, you will be notified by the 59th Clinical Research Division Resource Manager (292-7924) concerning the status of the requested funds. **YOU ARE NOT AUTHORIZED TO USE YOUR SECTION'S O&M FUNDS.**

6. IAW DoDI 3216.02_AFI 40-402, Enclosure 3, Section 3.a, this research will be reported to AFMSA/SGE-C and documented in subsequent IRB minutes. If SGE-C disagrees with the Designated Reviewer's determination, the research study may be temporarily suspended until resolution.

7. If you have any questions, the POC is Sa Martinez at 292-4210 or sa.martinez.ctr@us.af.mil. Please include your project title and reference number in all correspondence or inquiries.

ESTRADA.ROY.R.1129533770
I determined this activity to be Exempt Cat 4 human research with HIPAA waiver approved
2015.08.17 13:33:09 -05'00'

Roy Estrada, PhD
Designated Reviewer

DEPARTMENT OF DEFENSE
HCE HEARING CENTER OF EXCELLENCE

DATA REQUEST AND USE AGREEMENT FORM

This data request and use agreement form is designed to ensure requests are compliant with regulatory requirements, including Department of Defense ("DoD") Health Information Privacy Regulation (DoD 6025.18-R), which implements the Health Insurance Portability and Accountability Act ("HIPAA") Privacy Rule, and DoD Privacy Program (DoD 5400.11-R), which implements the Privacy Act of 1974, as amended.

This application to request data must be completed by both the Applicant and the Government Sponsor, as defined below. Each will be asked to sign this form in order to certify the accuracy of the completed agreement.

Directions: Fill out all applicable areas of the form, sign, and submit via e-mail (scanned attachment with signature), or mail to:

DoD Hearing Center of Excellence
AFMOA/SGBH
Wilford Hall Ambulatory Surgical Center
2200 Bergquist Dr. Suite 1 (Room #6B75)
Lackland AFB, TX 78236-9908

EMAIL:
Stacy.leonard.ctr@us.af.mil (DSN) 554-6763 (COMM) (210)292-6763

SECTION A: REQUESTOR INFORMATION

A1. Applicant:

- The Applicant is the individual who will have primary oversight and responsibility for handling the data requested in this agreement.
- For contract-driven requests involving subcontractors, the Applicant must be an employee of the prime contractor.
- For projects with more than one prime contractor, an agreement must be completed by **each prime contracting organization that will have custody of the requested data.**

Name: (Last, First MI)	Adrienne Laury
Rank/Grade: *If Applicable	O4/MC
Position/Title:	Principal Investigator
Organization:	Otolaryngology/ Lackland
Office Symbol:	
Email Address:	adrienne.m.laury.mil@mail.mil
Phone: (Commercial & DSN if applicable)	6105331282 (c); 210-594-2630 (p)

A2. Government Sponsor: The Government Sponsor is the point of contact within Armed Service who assumes responsiblity for the contract, grant, agreement, or other project for which data is requested in agreement.	
Name: (Last, First MI)	See Above
Rank/Grade: *If Applicable	
Position/Title:	
Organization:	
Office Symbol:	
Email Address:	
Phone: (Commercial & DSN if applicable)	

A3. List the name(s) of each prime contracting organization and subcontracting organization that will have access to or use of the data requested:	
Prime Contracting Organization	
Subcontracting Organizations	

A4. Source of Data Request:

- ☐ **Contract or Grant**
- ☒ **Military Site**
- ☐ **CRADA Partner**
- ☐ **Other** _____

Contract/Grant/CRADA/Other Project Number(s)	
Current Option Year Period of Performance Dates	
Expiration Date(s) of Contract/ Grant/CRADA/Other Project	

SECTION B: INTENDED USE OF REQUESTED DATA

B1. Purpose of the Tasking/Study/Project Requiring Data (Please provide specific reasons for needing requested data):

Balloon Sinusplasty: Indications, Outcomes, and Complications in the Department of Defense

B2. IS THE REQUESTED DATA USED TO SUPPORT RESEARCH?

☒ **YES** ☐ **NO**

If "Yes," then comply with statements in Section E.

Research is defined by the Code of Federal Regulations (CFR §46.102) as: a systematic investigation, including research development, testing and evaluation, design to develop, or contribute to generalizable knowledge.

B3. Please Provide Specific Information on how the data will be stored:
(Describe in detail computer security precautions and physical security of facilities and containers where the data is placed for safekeeping.)

File containing patient identifiers will be password protected and sent via encrypted email. File will then be stored on the H drive of the lackland network, only accessible with CAC by investigators.

B4. PLEASE LIST INDIVIDUALS AUTHORIZED TO ACCESS THE REQUESTED DATA:
(List any additional authorized users on a separate page and attach to this request.)

Name	Rank	Organization	Position/Title
Joshua Stramiello	O1/MC	Otolaryngology/ Lackland	Research Assistant

SECTION C: DATA REQUEST SPECIFICS

C1. TYPE OF DATA:
Check all that apply. If you are unsure of the appropriate sources for your data request please contact the HCE Informatics team for assistance prior to completing this section.

- ☐ 1. CDM (From MDR)
- ☐ 2. DMHRSi
- ■ 3. M2
- ☐ 4. MDR
- ☐ 5. DODTR-Acoustic Module
- ☐ 6. DMSS
- ☐ 7. DOEHRS-HC
- ☐ 8. DEOHRS-IH
- ☐ 9. DOEHRS-DR
- ☐ 10. Other (Please Specify Below)

C2. Other Data Type(s)

C3. TIME FRAME: (e.g., CY, FY, etc.)

CY 2011-2014

C4. SELECTION CRITERIA/POPULATION: (e.g., AD, men, enrollees, etc.)

☐ Check here if specific criteria are listed separately and provide the name of attached document.

AD Only, Encounters within date range that contain any of the following procedure codes:
31295, 31296, or 31297

C5. DATA ELEMENTS: (List in a separate sheet, if necessary)

☐

Person ID, Pseudo Person ID, Beneficiary Name, Date of Birth, Encounter Date, Treatment DMIS ID, Treatment DMIS ID Name, MEPRS 4, MEPRS 4 Description, Beneficiary Category Common, Beneficiary Category, Age Group Common, Calendar Year, Procedure Fields 1-10 and Procedure Short Names.

C6. OUTPUT FORMAT: (e.g., Microsoft Excel, comma delimited flat file, etc.)

Excel

C7. OTHER SPECIFIC INSTRUCTIONS: (Complete and detailed instruction can expedite the process.)

☐ Check here if specific instructions are listed separately and provide the name of attached document.

C8. DOES THE REQUESTED DATA REQUIRE MATCHING ON PERSONAL IDENTIFING INFORMATION (PII)? IF YES PLEASE INCLUDE EXPLANATION/JUSTIFICATION

(Check One) ☒ **YES** ☐ **NO**

Patient identifiers are needed to look up patients records in AHLTA to support IRB approved protocol to study outcome

SECTION D: DATA USE AGREEMENT (For all data requests)

1. The requestor will not disclose, release, or otherwise disseminate the data to anyone not covered by this document. Access to this data will be limited to a minimum number of individuals necessary to achieve the purpose and to those individuals on a need-to-know basis.

2. The requestor is aware of the Privacy Act of 1974 and the Health Insurance Portability and Accountability Act of 1996 pertaining to safeguarding personal information. The requestor will assure these requirements are followed to protect the confidentiality of the data and prevent unauthorized disclosure, use, or access to it.

3. The requestor agrees that no findings, listing, or information derived from the requested data, with or without identifiers, may be released if such findings, listing or information contain any combination of data elements that might allow the deduction of an individual's identification without first obtaining written authorization.

4. Data will only be used for the specified purpose.

5. Data will not be incorporated into any database of record.

6. It is the requestor's responsibility to destroy all copies of the data after it fulfills its intended use or as stated in IRB approved protocol.

7. The requestor must certify the destruction of the data files in writing within 30 days of completion of the specified purpose and send this certification to:

DoD Hearing Center of Excellence
AFMOA/HCE
Wilford Hall Ambulatory Surgical Center
2200 Bergquist Dr. Suite 1 (Room #6B72)
Lackland AFB, TX 78236-9908

8. No data or parts of data will be retained when the files are destroyed.

SECTION E: DATA USE AGREEMENT (For data requests supporting research)

1. The requestor certifies the requested data will be used for research conducted in accordance with DoDI-3216-02 (http://www.dtic.mil/whs/directives/corres/pdf/321602p.pdf) and 32CFR219 (http://www.tricare.mil/hpae/_docs/32cfr219.pdf)

2. The requestor is aware federal regulations allow certain kinds of research to be exempt from full review by an Institutional Review Board (IRB), given that certain criteria are met. The requestor has reviewed these criteria in 32CFR219. In case this research meets the exemption criteria, the requestor must have applied for and received such exemption from an approved IRB. In these circumstances, the exemption letter and a copy of the IRB application are attached.

3. In the case this research does not meet the exemption criteria; the research protocol has undergone full review by an authorized IRB and has received approval. In this case, the authorization letter from the IRB and a copy of the IRB application are attached.

4. In the case IRB approval is pending DUA approval, this DUA can be signed and submitted to the authorizing IRB, however no data will be released until the IRB approval letter and a copy of the IRB application are received by the HCE.

5. A copy of the final report must be sent to DoD HCE within six weeks after completion for closure of the request.

SECTION F: ATTACHMENTS

PLEASE LIST ALL ATTACHMENTS TO THIS DOCUMENT

RESEARCH PROTOCOL AND IRB APPROVAL LETTER

SECTION G: SIGNATURES

The undersigned agree to the provisions in this document:

Signature of Data Requestor — Date: 9/1/15

Signature of Director/Chief of Organization Requesting Data — Date: 9/1/15

SECTION H: APPROVAL (DoD HCE internal use only)	
HCE Informatics Team Representative Name Stacy M. Leonard Signature **HCE Authorizing Official:** Name Signature	Position/Title Informatics Program Manager/Analyst Date 08-31-2015 Position/Title Date
Action (check one) ☐ **APPROVED**	☐ **DISAPPROVED**
Comments:	